

Real-Life Utilization of Real-Time Continuous Glucose Monitoring: The Complete Picture

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Abstract

Background:

Very few studies to date have analyzed the reasons why some people do not use real-time continuous glucose monitoring (RT-CGM) continuously, especially given its positive glycemic outcomes, or choose not to wear it at all, even after learning about its benefits.

Methods:

A questionnaire was designed to assess real-life use of and issues surrounding RT-CGM. Hemoglobin A1c (HbA1c) and duration of sensor use were also obtained from the patients' charts.

Results:

Fifty-eight subjects with type 1 diabetes (T1DM), average age 15.0 ± 4.8 years, T1DM duration 5.7 ± 3.8 years, HbA1c $8.8 \pm 2.1\%$, 50% with RT-CGM, were included in the analysis. Hemoglobin A1c was lower with increased RT-CGM use. Real-time continuous glucose monitoring was ordered to improve control. Users liked the continuous data. The most disliked part was pain and discomfort. Occasional users described RT-CGM as annoying, a hassle, and interfering with their lives. Reasons for discontinuing RT-CGM included problematic equipment and inaccuracy (64%), intrusion in life (36%), and insurance issues (29%). Twenty-one percent of nonusers reported RT-CGM to be inconvenient or a hassle or just did not want it. Fifty-two percent of subjects continue to use RT-CGM despite reported problems.

Conclusion:

Real-time continuous glucose monitoring is a beneficial tool for improving glycemic control, and many use it despite reported problems and hassles with current devices. However, this technology has not been wholeheartedly embraced by many individuals with T1DM, especially in youngsters, because of issues mentioned here. Based on the findings of this study, it is hoped that improvements will be made to RT-CGM technology so that more people with diabetes will embrace this beneficial tool.

J Diabetes Sci Technol 2011;5(4):860-870

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Abbreviations: (BG) blood glucose, (HbA1c) hemoglobin A1c, (RT-CGM) real-time continuous glucose monitoring, (T1DM) type 1 diabetes mellitus

Keywords: diabetes, glucose sensor, real-time continuous glucose monitoring, sensor dislikes, technology

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Introduction

Real-time continuous glucose monitoring (RT-CGM), which has been available since 2006, has created a paradigm shift in diabetes management. Many studies demonstrate the significant beneficial impact of this technology on glycemic control.¹⁻¹³ However, it is not enough to simply give people with diabetes a RT-CGM system, train them on its use, and send them home with it. They must actually use it for it to work. Studies show that improvements in hemoglobin A1c (HbA1c) are usually seen only when RT-CGM is used at least 60–70% of the time, and the greatest benefits are seen in those who are ≥ 25 years old.^{1,5,6,9,10} This is not to say that pediatric patients do not benefit from RT-CGM use. The DirecNet Study Group² and Danne and colleagues⁴ both noted that an increased frequency of RT-CGM use in the pediatric population was associated with better glycemic control and more metabolic benefits, such as decreased glucose variability and less hypoglycemia.¹²

What is not highlighted in these studies is the difficulty that the subjects had with sensor use. **Table 1** lists each major RT-CGM study and the number of subjects who had sensor-related difficulties, many of which led to study discontinuation.^{2,5,6,9,10,12-14} While sensor-related issues themselves were not reported to cause a high dropout rate, great difficulty with RT-CGM use was reported, especially in the pediatric population,^{2,12,14} and one study documented significant compliance issues.⁹

Going further behind the scenes in the DirecNet studies highlights some of the issues facing pediatric patients

with diabetes who try to use RT-CGM. In the 2007 study ($n = 30$), 10 problems were reported. The most frequent was that the families were too busy to give the attention that was necessary to the sensor ($n = 4$). Other problems included skin irritation, calibration difficulties, a lost receiver, a subject running out of sensor electrodes, bleeding at the site of insertion, and adhesion problems ($n = 1$ each).² In another study that discussed the process of educating families on RT-CGM, 57 patients made 476 phone calls in 3 months for sensor-related issues, including adhesion problems ($n = 56$), bleeding at the site ($n = 42$), discomfort ($n = 15$), and insertion difficulties ($n = 14$). There were 306 reports of skin and sensor issues in the 476 phone calls they fielded during their study.¹⁴ A third DirecNet study with 45 subjects reported calibration difficulties, bleeding at the insertion site, adhesion problems, discomfort, frequent alarms, and “just needing a break.”¹² The frequency with which these problems occurred was not reported.

Clinically, many patients who are started on RT-CGM stop using it shortly thereafter, despite some having noticeable improvements in glycemic control with sensor use. The reasons behind this have not been clearly documented or explored. This pilot prospective clinical research study was designed to describe factors associated with continuous use of RT-CGM, intermittent use of RT-CGM, discontinuation of RT-CGM, and not wanting to use RT-CGM in a pediatric and young adult population, with a focus on why patients are not yet embracing this beneficial technology.

Table 1.
Incidence of Sensor-Related Difficulties in Major Real-Time Continuous Glucose Monitoring Studies

Study	Discontinued study for potential sensor-related issues	Difficulties with RT-CGM use and/or alarms	Did not comply with study protocol and discontinued	Requested early study discontinuation or withdrawn
GuardControl ⁵	3.7% (6/162)	3.1% (5/162)	—	—
STAR 1 ⁶	4.1% (6/146)	—	1.4% (2/146)	2.7% (4/146)
STAR 3 ¹³	—	—	—	7% (32/485)
Juvenile Diabetes Research Foundation ¹⁰	1.6% (5/322)	—	—	—
RealTrend ⁹	15.2% (20/132)	—	41.8% (23/55)	—
DirecNet ^{2,12,14}	—	26.7% (12/45); 30% (9/30); 64.3% (306/476)	—	—

Methods

A questionnaire was designed by the researchers to assess glucose sensor knowledge, use, likes, dislikes, and what improvements patients thought were necessary (**Appendix A**). The questions were mostly open-ended so that nothing would be missed. As subjects could give more than one answer for many of the questions, some of the results add up to more than 100%.

Patients with T1DM from a major urban, multi-ethnic, hospital-based pediatric diabetes practice were approached to participate in this study. The patient population at this practice is 60–70% Medicaid or Medicaid managed care (state/government insurance). The diabetes providers at this center embrace diabetes technology and are very proactive about getting their patients to use it. Starting patients on insulin pumps at the time of diagnosis is standard practice, and the providers encourage sensor use. Exclusion criteria were patients/families unable to understand English, patients with type 2 diabetes, and patients who were in the midst of ordering a RT-CGM device, as they did not clearly fall into any group being analyzed.

Once consent was obtained, the sensor questionnaire was given to the family to be completed. They could either complete it at the time of their office visit or take it home and mail it back. The questionnaire was completed by either the subject or their parent. Demographic information was collected from both the questionnaire and from the subject's medical records. Additionally, the HbA1c that was done closest to the time of questionnaire completion was obtained from the subject's chart. Date of sensor start and duration of use were cross-checked with the subject's chart. Data analysis was done using Microsoft Excel 2003. All results are expressed as mean \pm standard deviation. This study was approved by the institutional review board of the medical center where it was executed.

Results

A random, cross-sectional sample of 60 subjects agreed to participate in this study. Of these subjects, 2 filled out the questionnaire incorrectly—one discussed her insulin pump instead of a sensor, and the other discussed his blood glucose (BG) meter. Fifty-eight questionnaires were satisfactorily completed and are included in this analysis. Demographics appear in **Table 2**.

Fifty percent ($n = 29$) of subjects had RT-CGM systems at home. Six subjects used their RT-CGM continuously, 8 used it intermittently, and 14 youngsters had used it at

Table 2.
Demographics

<i>N</i>	58
Age (range)	15.0 \pm 4.8 years (1.9–25.8 years)
Sex	28 male/30 female (48%/52%)
Ethnicity	Caucasian: 59% Hispanic: 14% Asian: 7% Black: 12% Middle Eastern: 9%
Diabetes duration (range)	5.7 \pm 3.8 years (0.5–14.0 years)
HbA1c (%) (range)	8.8 \pm 2.1 (5.3–14.0; $n = 52$)
# of BG readings/day (range)	4.8 \pm 2.3 (0.6–12)
Treatment modality	Insulin pump: 84% Both pump and multiple daily injections: 7% Multiple daily injections: 9%
# of sensors (%)	29 (50%)

some point but no longer did. One subject had received the sensor but never wore it because the transmitter looked too big. Demographics by sensor use group appear in **Table 3**.

While previous use of RT-CGM did not show significant benefits to glycemic control compared to never having used RT-CGM ($p = .27$), continuing to use a sensor at least some of the time had a significant impact on lowering HbA1c ($p = .001$). Those who used sensors sometimes had had diabetes for a significantly shorter duration of time than those who used to use RT-CGM ($p = .02$). No other significant differences were noted between groups on the basis of age, sex, duration of diabetes, or frequency of BG monitoring.

The majority of the 58 subjects and their families were familiar with RT-CGM. Eighty-five percent reported having discussed RT-CGM with the diabetes team, 55% could accurately describe how it worked, and an additional 26% gave a partially accurate description. Only 19% of subjects were unable to describe how the system worked.

The most common reason for wanting a glucose sensor was to improve glycemic control (45%). Other reasons included clinician recommendation (24%), a perception that RT-CGM use would make diabetes management easier (17%), a desire for less finger stick BG monitoring (14%), to detect hypoglycemia (10%) and hyperglycemia (3%), and, for 3 subjects, because they just “loved the idea” of having a device that could give them glucose

Table 3.
Demographics by Sensor Use Group

	No sensor	Yes: never wore	Yes: always	Yes: sometimes	Yes: used to
<i>N</i>	29	1	6	8	14
Age (years)	15.3 ± 5.2	14.7	16.2 ± 5.8	13.4 ± 4.5	15.0 ± 4.2
Sex	14 male/15 female	Male	3 male/3 female	2 male /6 female	8 male/6 female
Ethnicity	45% Caucasian	Caucasian	100% Caucasian	63% Caucasian	64% Caucasian
Diabetes duration (years)	5.5 ± 3.6	4.3	6.8 ± 5.7	3.5 ± 2.8 ^a	7.2 ± 3.6 ^a
HbA1c (%)	9.7 ± 2.4 ^b	9.4	6.7 ± 1.1 ^c (whole)	8.2 ± 1.3 group =	8.6 ± 1.5 8.1 ± 1.5) ^b
BG/day	4.8 ± 2.1	1	4.1 ± 2.3	5.4 ± 1.9	5.2 ± 2.8
Treatment	79% CSII	CSII	100% CSII	100% CSII	79% CSII

CSII, continuous subcutaneous insulin infusion
^a $p = .02$ sometimes vs used to (all other comparisons of diabetes duration $p =$ not significant).
^b $p = .009$.
^c $p = .04$ vs sometimes and $p = .008$ vs used to.

readings every few minutes and alert them about out-of-range blood sugars.

On average, subjects who had sensors had used them for 7.4 ± 9.7 months, with a range of 0 days to 3 years. Real-time continuous glucose monitoring was used at least occasionally by 48% of subjects. "Occasionally" was defined by users as once a month, before checkups, when their BG was variable, and when they want better control.

Once subjects had started on RT-CGM, the leading cause for sensor discontinuation was problematic equipment, which was reported by 43% of sensor users. Problematic equipment and inaccuracy together accounted for 64% of reasons given for sensor discontinuation. The second leading single cause for sensor discontinuation was that the subjects found RT-CGM to be too intrusive in their lives (36%). It was "stressful, annoying, uncomfortable, and made life harder." Insurance issues were the third leading reason (29%). Other reasons for sensor discontinuation included inaccuracy (21% when not combined with any other reason), too many alarms (21%), the subject was too skinny and/or two sites was too many (14%), skin irritation (14%), and pain/discomfort of RT-CGM use (7%).

Most subjects did not use RT-CGM continuously, despite the benefits noted in the literature.¹⁻¹³ The overwhelming reason for intermittent sensor use was that subjects found RT-CGM to be annoying, a hassle, and interfering with their lives. This was reported by 63% of subjects.

Additional reasons for intermittent sensor use, each reported once (13%), were pain, insurance issues, to catch trends, and because it was suggested by the diabetes clinician.

When the numbers of intermittent sensor users and those who discontinued sensor use were combined, 45% reported RT-CGM to be annoying, stressful, uncomfortable, a hassle, and interfering with their lives. Pain and wearing a second site were not often identified as the cause for limited sensor use or sensor discontinuation. Each was reported by only two subjects (10%). However, a specific inquiry into comfort of RT-CGM use had varying and not always favorable responses (Table 4).

Nevertheless, 76% of subjects who owned a glucose sensor believed that using RT-CGM helped them to manage their diabetes better because of the continuous data, trend information, and warnings for hypoglycemia and hyperglycemia. Some adolescents stated that using RT-CGM reminded them to bolus. One subject wrote,

I compare a person that doesn't have a [continuous glucose monitor] to a person walking on a tightrope with closed eyes. Even though he thinks his blood sugars are in normal range, he never experienced to know how exactly... his blood sugar ranges... When you have a [continuous glucose monitor], you could actually spot the problem before visiting your doctor. You can't go wrong with a [continuous glucose monitor]; it pays to give it a try.

Table 4. Reported Comfort of Real-Time Continuous Glucose Monitoring Use			
	Insertion	Wearing site	Carrying monitor
Painful, uncomfortable	38%	28%	14%
Too big, annoying, bulky, heavy	—	14%	17%
Skin irritation	—	17%	—
Adhesion problems	—	10%	—
Problem where to keep it	—	—	7%
Frightening	3%	—	—
Varies	3%	—	—
Ok	34%	28%	14%
Another monitor to carry	—	—	7%
Painless, easy, comfortable	10%	14%	10%
Monitor = pump	—	—	41%

On the opposite side of the spectrum, 17% of subjects who owned a glucose sensor believed that it did not help with their diabetes management because of inaccuracy, calibration problems, too many alarms, they were already checking BG frequently, or because it was too big and bulky so they did not wear it.

Reported beneficial features of RT-CGM, divided by those who still use the technology at least occasionally and those who used to use it, appear in **Figure 1**. Reported dislikes, divided into the same two groups, appear in **Figure 2**.

Half of the subjects surveyed ($n = 29$) did not use a glucose sensor. The reasons for this included that they just did not want it or thought it was a hassle or inconvenient (21%), insurance issues (17%), they were unaware about RT-CGM (17%), they did not want a second site (14%), they had not ordered it yet or were still considering whether or not they wanted this technology (14%), or they did not want to carry two devices (7%). One subject did not want RT-CGM because he/his parent thought it was inaccurate, and one more did not want to order RT-CGM for their child because he was so little. An additional 17% of subjects did not identify any reasons why they did not want RT-CGM. At least three subjects ordered glucose sensors as a result of participating in this study.

One possible issue with RT-CGM use is concerns about the patient’s privacy. Twenty-eight percent of subjects in this study were concerned that someone might see their

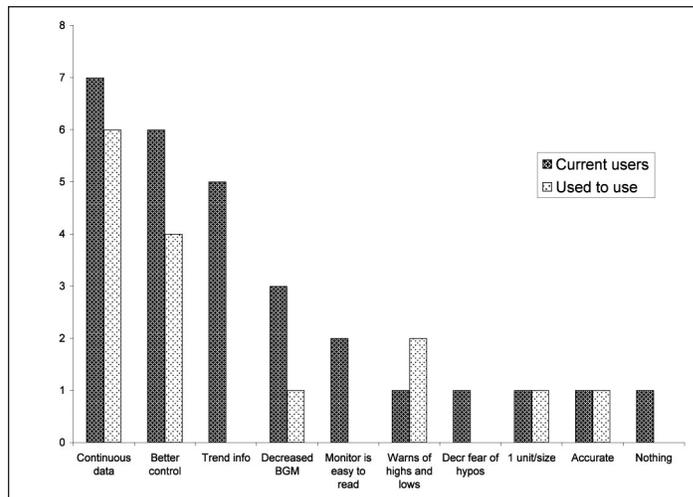


Figure 1. Reported beneficial features of RT-CGM. BGM, blood glucose monitoring; Decr, decreased.

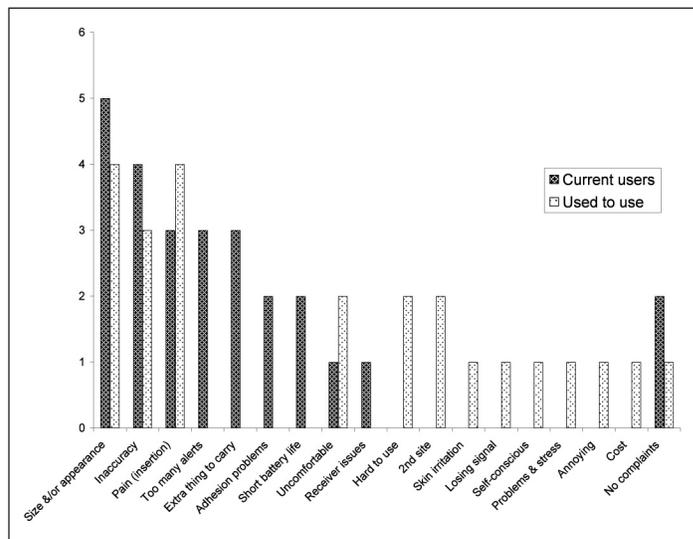


Figure 2. Reported dislikes of RT-CGM.

sensor or hear it beep to signal an out-of-range glucose value. When divided by group, 24% of nonusers and 31% of RT-CGM users were concerned about this (33% of continuous users, 38% of occasional users, and 29% of previous users).

Insurance coverage was thought to be another potential hurdle to RT-CGM use. However, only 19% of subjects in this study reported insurance problems. Insurance plans of eight subjects would not cover RT-CGM at all, and plans of five subjects would not cover enough sensor electrodes per month. Of those who stopped using their sensors, 43% reported insurance issues. The main insurance problem, reported by 83% of those with insurance issues, was not enough sensor electrodes being covered per month. Twenty-nine percent of subjects in this study invested in a RT-CGM system and paid for

it out of pocket, but the costs became so prohibitive that they could not afford to continue to use it.

Wearing two sites did not have a large impact on sensor use, discontinuation, or nonuse. Only 14% of subjects chose not to order a RT-CGM device because of two sites. From the RT-CGM users group, two subjects stopped using RT-CGM because of two sites, and an additional two subjects stopped using RT-CGM because the subject did not have enough fat and/or "real estate" on the body.

Pain was the most disliked part of using RT-CGM. Four subjects (14%) discontinued RT-CGM as a result.

Sensor inaccuracy compared to finger stick BG measurements was mentioned by 14% of subjects. One subject never ordered a RT-CGM system, and three subjects stopped using RT-CGM because of inaccuracy. However, four subjects continued to use it despite these problems.

When RT-CGM users were asked what improvements or changes to the system they would recommend, they provided a long list of suggestions that were grouped into six categories. All comments were mentioned once unless otherwise specified. For the sensor electrode and transmitter, users would like less pain on insertion and increased ease of insertion ($n = 4$), something to secure the electrode and/or transmitter better ($n = 3$), a longer sensor electrode life ($n = 2$), shorter calibration time, improved signal transmission, easier and less painful sensor electrode removal, and to combine the sensor electrode with the pump's infusion set. Regarding size, users would like the system to be smaller overall ($n = 6$), a smaller transmitter ($n = 3$), a less bulky receiver, and a smaller introducer needle. Six subjects wished for improved accuracy. Receiver requests included a waterproof receiver and a longer battery life. Regarding RT-CGM software, users would like for the system to be less difficult to calibrate, to beep less, not to beep at all when it is set to vibrate, have increased functions (these were not specified), and to work with a smart phone via Bluetooth or WiFi. Miscellaneous requests included making the software Mac-compatible, combining the RT-CGM system with the insulin pump ($n = 2$, these subjects were using the Dexcom system), making it cost-effective, decreasing the amount of time the sensor needs to be worn, and a desire for a functional, patient-ready closed-loop system.

Discussion

In a technologically savvy group of diabetes clinicians and patients, half of the patients surveyed had ordered

a RT-CGM system. The number one reason for sensor use was to improve glycemic control, and most believed it did. As with other RT-CGM studies,¹⁻¹³ this study also found significant improvements in HbA1c with more frequent sensor use. The percentage of time that RT-CGM was used was not measured; however, subjects' self-reports of continuous use, intermittent use, and previous use were incorporated into the data analysis.

The most disliked part of RT-CGM was the pain and discomfort involved in using it. Intermittent users described RT-CGM as annoying, a hassle, and interfering with their lives. Overall, RT-CGM use was reported as being more uncomfortable than not. Although other studies have yet to specifically examine sensor use issues to this degree, subjects in the RealTrend and DirecNet studies experienced some similar problems.^{2,9,10,12,14}

The number one reason for discontinuing RT-CGM use was problematic equipment and inaccuracy, which, when combined among subgroups, was reported by 64% of subjects. Other leading reasons for RT-CGM discontinuation were its intrusion in the users' lives and insurance issues. The DirecNet Study Group¹² found that those who had early acceptance of RT-CGM were more likely to continue using it after 6 months. As ours was a cross-sectional study, no information is available regarding early acceptance of RT-CGM. Our study also differed from this DirecNet study in how well the children tolerated RT-CGM. They found RT-CGM to be "generally well-tolerated,"¹² while half of the subjects in our study who had received a glucose sensor had stopped using it by the time they completed the survey.

Based on subjects' lists for improvements to the system, the sensor electrodes and transmitters need the most improvement. Sensor electrode introducer needles are currently 21–26 gauge,¹⁵ compared with pump infusion set and insulin injection needles, which are 28–32 gauge. Adhesion of the sensor electrode and transmitter unit was another issue, both in this study and in the DirecNet studies.^{2,12,14}

From RT-CGM nonusers, 21% reported RT-CGM to be inconvenient or a hassle or just did not want it. An additional 17% each reported insurance issues or that they were unaware of RT-CGM or gave no reason.

Nonusers had significantly higher HbA1c levels than sensor users. No inferences can be made from this, as nonusers did not differ from users on the basis of duration of diabetes, frequency of BG monitoring, or any other

demographic characteristic. Further exploration will need to be done in this group to better describe them.

Sensor users liked the continuous data that RT-CGM provides. Over half of the sensor users in this study (52%) continue to use RT-CGM despite the reported problems. One subject put it best, at the end of her questionnaire: "You didn't ask me about my appreciation, which actually can't be written down on paper."

This study was a pilot study with a relatively small sample size. Questionnaires were given to families and could be completed by either the child or the parent. We did not inquire about or identify who completed the questionnaire. Parents may have different perceptions about RT-CGM than their children and could have biased the data. As a result of this study, more questions have emerged that will need to be answered by future investigations.

Conclusions

Real-time continuous glucose monitoring is a beneficial tool for improving glycemic control in patients who use it, and many use it despite reported problems and hassles with current devices. However, this technology has not been wholeheartedly embraced by many individuals with T1DM, especially in youth, because of issues such as problematic equipment, inaccuracy, pain, discomfort, annoyance, and the degree to which it is perceived to interfere in the daily lives of the patients. These issues affect whether or not innovative, seemingly helpful diabetes technologies will be embraced by patients who would benefit from them and need to be evaluated when designing new products. Larger studies inquiring about issues surrounding RT-CGM use, as well as possibly differing perceptions of patients versus caregivers, need to be done to better describe these groups and so improvements to RT-CGM devices and technology can be made.

Disclosure:

Preliminary results of this study were presented at the Third Annual Advanced Technologies and Treatments for Diabetes meeting in Basel, Switzerland, in February 2010.

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Appendix A. Sensor Questionnaire



Initials: _____

DOB: _____

Age: _____

Sex (please circle): Male / Female

Today's Date: _____

Real-Time Continuous Glucose Monitoring (Sensor) Questionnaire

1. How long have you had diabetes? _____
2. What do you use to treat your diabetes (syringes, pens, pump & which insulin(s))? _____

3. How often do you check your blood sugars by finger stick? _____ times per day
4. Has anyone in our Endocrinology office spoken to you about using glucose sensors or real-time continuous glucose monitoring (RT-CGM), to help you better manage your diabetes? (Please circle) YES NO
5. What were you told by the Maimonides Pediatric Endocrinology team about sensors? _____

6. Please tell us what you know about how continuous glucose monitoring works. _____

7. For whom do you think using a sensor would be most helpful? _____
8. Do you have glucose sensor/real-time continuous glucose monitor? YES NO
If no, why not? _____
9. If you were to wear a sensor, are you concerned that someone else might see your sensor or hear it beep? _____

If you answered NO to question #8 above, thank you for your participation. You are now done with the questionnaire. If you answered YES to question #8 above, please continue below.

10. Which product are you using? (please circle)

- a. MiniMed pump with sensor
- b. MiniMed Guardian
- c. DexCom
- d. Freestyle Navigator

11. Why did you choose to use a glucose sensor/continuous glucose monitoring? _____

12. For how long have you been using your sensor? _____

13. How long do you leave your sensor electrode (sticker) in before you change it? _____

14. How often do you look at your sensor to see what your sugar is? _____

15. How comfortable is it to wear and use your sensor/continuous glucose monitor?

- a. Inserting the electrode _____
- b. Wearing the site/sticker _____
- c. Carrying the monitor _____

16. If you use a sensor, how often do you use it? (please circle)

- a. All the time (continuously)
- b. Sometimes
- c. I used to use it, but I don't use it any more.

17. If you answered "sometimes" to question #16 above, when do you use your sensor? _____

Why do you use it only sometimes? _____

18. If you used to use your sensor but don't use it any more, for how long did you use it? _____

Why did you stop using it? _____

19. Are you wearing your continuous glucose monitor now? YES NO

20. If you answered "no" to question #19 above, why not? _____

21. What do you like about your sensor/real-time continuous glucose monitor? _____

22. What do you dislike about it? _____

23. Do you find that using your sensor helps you to better manage your diabetes? YES NO

24. If you answered "YES" to question #23 above, please explain how. (An example would be helpful, if you can think of one.) _____

25. If you answered "NO" to question #23 above, please explain why. (An example would be helpful, if you can think of one.) _____

26. What improvements would you like to see made to the sensor/real-time continuous glucose monitor? _____

27. Is there anything about using the sensor which, if it wasn't changed, may cause you to stop using it? _____

28. How good is the customer support from the company? _____

29. Is there anything else that we didn't ask about that you would like to tell us? _____

Thank you for your participation!